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Department of Health and Human Services

Bureau of Medical Services

Chapter 503

**MAINE CERTIFICATE OF NEED
PROCEDURES MANUAL
for Health Care Facilities
(other than Nursing Care Facilities)**

**EFFECTIVE
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TABLE OF CONTENTS

TABLE OF CONTENTS	i
TOPICAL INDEX	iii
EXPLANATORY PREFACE	v
1. INTRODUCTION	1
RULES	3
2. SCOPE OF RULES	4
3. DEFINITIONS.....	5
4. THE SCOPE OF CERTIFICATE OF NEED - COVERED ACTIVITIES	12
1. Certificate of Need Required	12
2. Exceptions.....	13
3. Subsequent Review following Changes in Project	14
4. Subsequent Review following Approval	15
5. Divisions Prohibited	15
6. Time Spans Specified	15
5. IMPLICATIONS OF NONCOMPLIANCE.....	16
1. Withholding of License	16
2. Withholding of Funds	16
3. Injunction.....	17
4. Penalty	17
6. APPLICATION PROCESS FOR A CERTIFICATE OF NEED	18
1. Letter of Intent	18
2. Application Filed	18
3. Application Content	19
4. Application Complete	19
5. Revision of an Application	19
6. Public Notice: Public Informational Meeting	20
7. Voluntary Withdrawal of Application	20
8. Filing Fee	21
9. Suspension of Review.....	21
10. Reapplication	21
11. Maintenance of a Mailing List.....	21
7. REVIEW PROCESS.....	23
1. Type of Review/Notification Of Applicant	23
2. Review Cycles	23
3. Capital Investment Fund Review Procedures	24
4. Public Hearing	24
5. Preliminary Staff Analysis.....	25
6. Final Department Staff Analysis.....	25
7. Reviews.....	25

TABLE OF CONTENTS

8.	Public Necessity.....	26
9.	Simplified Review and Approval Process	26
10.	Capital Expenditures.....	27
8.	APPROVAL: RECORD	28
1.	Basis For Decision	28
1-A	Review Cycle	28
2.	Communications	28
3.	Limited Communications	28
4.	Decision	28
5.	Record.....	29
6.	Maintenance of the Record	29
7.	Conditional Approvals.....	30
8.	Emergency Certificate Of Need.....	30
9.	CONSULTATION.....	31
1.	Consultation on New Technologies and Needs	31
10.	PRINCIPLES GOVERNING REVIEWS.....	32
1.	Determinations Required	32
11.	SCOPE OF CERTIFICATES OF NEED ISSUED.....	36
1.	Application Determination.....	36
2.	Maximum Expenditure	36
3.	Periodic Review	36
12.	DEPARTMENTAL RECONSIDERATION	37
1.	Timing For Request	37
2.	Petition For Reconsideration.....	37
3.	Hearing.....	37
4.	Conduct of Hearing.....	37
5.	Decision	37
13.	JUDICIAL REVIEW	39
1.	Remedy	39
2.	Finality	39
3.	Competitive Reviews	39
14.	IMPLEMENTATION REPORTS	40
1.	Final Plans and Specifications	40
2.	Periodic Reports.....	40
3.	Summary Report	40
4.	Cost and Utilization Reports.....	40
5.	Department Action.....	40
15.	OTHER PROVISIONS.....	41
1.	Conflict of Interest.....	41
2.	Public Information	41
3.	Cost-of-Living Adjustment.....	41
4.	Federal Funding	41

TOPICAL INDEX

Access to care	5	Divisions prohibited	15
Acquisition of control	26	Duplicate existing services or facilities	34
Acquisitions of major medical equipment	12	Economic feasibility.....	32
Advisory note.....	12	Emergency certificate of need	30
Ambulatory surgical facility	5	Exceptions	13
An increase in the number of inpatient beds.....	34	Expenditure minimum for annual operating costs	7
Annual operating costs.....	5	Explanatory preface	vi
Annual report	41	Extraordinary project.....	24
Application complete.....	19	Extroardinary project	7
Application content.....	19	Federal funding.....	41
Application determinative.....	36	Filing fee.....	20
Application filed	18	Final department staff analysis	25
Application process for a certificate of need (chapter 6)	18	Final plans and specifications.....	40
Appropriately capitalized expenditures	5	Finality.....	39
Approval: record (chapter 8).....	28	Fit, willing and able	32
Bed capacity.....	5	Generally accepted accounting principles	7
Bed complement	5	Good faith efforts in meeting the voluntary price and cost targets established by the dirigo health reform act	34
Capacity of the applicant to support the project financially.....	32	Health care facility.....	7
Capital expenditure	5	Health maintenance organization	7
Capital investment fund	5	Health need	8
Capital investment fund review procedures.....	24	Health planning.....	8
Certificate of need required.....	12	Health services.....	8
Changes in bed complement	13	Health status	8
Commenced/commencement.....	6	Hospital.....	8
Communications	28	Hospital project.....	8
Competitive reviews	39	Hospital swing bed	8
Conditional approvals	30	Implementation reports (chapter 14)	40
Conduct of reconsideration hearing.....	37	Implications of noncompliance (chapter 5)	16
Conflict of interest	41	Injunction.....	17
Consistent with the State health plan.....	33	Introduction (chapter 1).....	1
Construction.....	6	Investment in and/or use of an electronic medical records system with an hl7 interface	34
Consultation (chapter 9).....	31	Judicial review (chapter 13).....	39
Content of the letter of intent	18	Large project.....	8
Cost.....	6	Less costly, alternative technologies or methods of service delivery	32
Cost and utilization reports	40	Letter of intent	18
Cost-of-living adjustment	41	Letter of intent is deemed withdrawn	18
Criteria for determining when it is not practicable to complete a review within 90 days.....	25	Life safety codes; previous certificates of need	26
Criteria for subsequent review	14	Limited communications	28
Definitions (chapter 3)	5	Maine health data organization.....	33
Department.....	7		
Department action.....	40		
Departmental reconsideration (chapter 12).....	37		
Determinations required	32		
Development	7		

TOPICAL INDEX

Maintenance of a mailing list of persons who have requested notification of the beginning of a review	21	Projects that contribute to lower costs of care and greater efficiencies	33
Maintenance of the record	29	Projects that protect public health and safety ..	33
Maintenance projects	26	Public hearing	24
Major medical equipment	8	Public information	41
Maximum expenditure	36	Public necessity	26
Modification.....	9	Public need	32
Monthly activity reports.....	18	Public notice; public informational meeting....	20
New health service	12	Purposes of the act.....	1
New health service	9	Reapplication	21
Non-applicability determinations.....	19	Reconsideration hearing	37
Non-hospital project.....	9	Reconsideration decision.....	37
Non-priority projects.....	34	Record.....	29
Nursing facilities.....	13	Regular basis.....	11
Nursing facility	10	Rehabilitation facility	11
Obligation	10	Related projects	13
Offer.....	10	Remedy.....	39
Operating costs.....	10	Replacement equipment.....	11
Order to the application process.....	18	Review cycles	23
Orderly and economic development.....	32	Review must be completed by	25
Other circumstances.....	13	Review process (chapter 7).....	23
Other provisions (chapter 15)	41	Revision of an application	19
Penalty	17	Rules	3
Periodic reports	40	Scope of certificate of need - covered activities (chapter 4)	12
Periodic review (following con issuance).....	36	Scope of certificates of need issued (chapter 11)	36
Person.....	10	Scope of rules (chapter 2)	4
Person directly affected by a review	10	Significant change in financing	11
Petition for reconsideration.....	37	Simplified review and approval process.....	26
Predevelopment activity.....	11	Small project.....	11
Preliminary staff analyses	25	State health plan.....	11
Principles governing reviews (chapter 10).....	32	Subsequent re periodic review view following approval.....	15
Priority criteria	33	Subsequent review following changes in project	14
Procedures for subsequent review.....	14	Summary reports.....	40
Project	11	Suspension of review	21
Project will be accessible to all residents.....	32	Table of contents	i
Project will have a positive impact on the health status indicators	32	Time spans specified	15
Project will provide demonstrable improvements in quality and outcome measures.....	32	Timing for request	37
Project will substantially address specific health problems.....	32	Transfer of ownership.....	12
Projects that advance access to services and reflect a collaborative, evidence-based strategy	34	Type of review/notification of applicant	23
		Voluntary withdrawal of application	20
		Withholding of funds.....	16
		Withholding of license.....	16

EXPLANATORY PREFACE

This volume of the Maine Certificate of Need Procedures Manual is a comprehensive compilation of the major statutory and regulatory provisions governing the Maine Certificate of Need program. It is intended to assist users by presenting in an organized manner relevant statutory material from the "Maine Certificate of Need Act of 2002" as well as the "Dirigo Health Reform Act." Users are urged to contact the Department of Health and Human Services at the address on page 2 for information on any additional materials that may be relevant to the development of a specific project.

CHAPTER 1: INTRODUCTION

The One Hundred and Eighth Legislature found that unnecessary construction or modification of health care facilities and duplication of health services are substantial factors in the cost of health care and the ability of the public to obtain necessary medical services.

The One Hundred and Twentieth Legislature passed "An Act to Strengthen the Certificate of Need Law," 22 M.R.S.A. c. 103-A Sec. 326, et seq., which became law on July 25, 2002.

The One Hundred and Twenty-First Legislature passed "An Act to Provide Affordable Health Insurance to Small Businesses and Individuals and To Control Health Care Costs," also known as the "Dirigo Health Reform Act", which became law beginning in September 2003.

The purposes of the Certificate of Need Act, stated at 22 M.R.S.A. Sec. 327, sub-Sec. 2, A-I, are to:

- A. Support effective health planning;
- B. Support the provision of quality health care in a manner that ensures access to cost-effective services;
- C. Support reasonable choice in health care services while avoiding excessive duplication;
- D. Ensure that State funds are used prudently in the provision of health care services;
- E. Ensure public participation in the process of determining the array, distribution, quantity, quality and cost of these health care services;
- F. Improve the availability of health care services throughout the State;
- G. Support the development and availability of health care services regardless of the consumer's ability to pay;
- H. Seek a balance, to the extent a balance assists in achieving the purposes of this subsection, between competition and regulation in the provision of health care; and
- I. Promote the development of primary and secondary preventive health care services.

To accomplish these purposes, the Act establishes a review program whereby Certificates of Need may be issued for proposals falling within clearly defined limits.

The Department of Health and Human Services has assigned administrative responsibilities for the Certificate of Need program to the following bureau. Inquiries may be directed to:

Director
Bureau of Elder and Adult Services
Department of Health and Human Services
442 Civic Center Drive
11 State House Station
Augusta, Maine 04333-0011

Rules: The Department shall adopt any rules, standards, criteria, plans or procedures that may be necessary to carry out the provisions and purposes of this Act. The Department shall, to the extent applicable, take into consideration recommendations contained in the State health plan, other Departmental publications, and research acquired through consultation with persons with relevant skills and experience regarding:

- A. New medical technologies and the impact of those technologies on the health care delivery system in the State; and
- B. Unmet need for health care services in the State.

The Department shall provide for public notice and hearing on all proposed rules, standards, criteria, plans, procedures or schedules, pursuant to Title 5, chapter 375. Unless otherwise provided by this chapter, rules adopted pursuant to this chapter are routine technical rules defined by Title 5, chapter 375, subchapter II-A. The Department is authorized to accept any federal funds to be used for the purposes of carrying out this chapter. 22 M.R.S.A. Sec. 342.

This Procedures Manual has been designed to:

- (1) Acquaint interested persons with the requirements of the Certificate of Need Act;
- (2) Detail the various steps encountered in the review process; and
- (3) Refer the user to any other relevant rules, regulations, standards, criteria or plans of the Department and other pertinent State offices.

CHAPTER 2: SCOPE OF RULES

Scope of Rules. This Procedures Manual incorporates all the relevant statutory provisions within the "Act to Strengthen the Certificate of Need Law" enacted by the One-Hundred and Twentieth Legislature as well as the provisions within the "Dirigo Health Reform Act" enacted by the One-Hundred and Twenty-First Legislature.

CHAPTER 3: DEFINITIONS

The following words and phrases shall have the following meanings:

1. **ACCESS TO CARE.** means the ability to obtain in a timely manner needed personal health services to achieve the best possible health outcomes balanced by the health system's resource limitations. Access to care may be influenced by many factors, including, without limitation, travel, distance, waiting time, available resources, availability of a source of care and the health status of the population served. 22 M.R.S.A. Sec. 328 (1).
2. **AMBULATORY SURGICAL FACILITY** means a facility, not part of a hospital, that provides surgical treatment to patients not requiring hospitalization. This term does not include the offices of private physicians or dentists, whether in individual or group practice. 22 M.R.S.A. Sec. 328 (2).
3. **ANNUAL OPERATING COSTS** for purposes of section 328, subsection 17-A, paragraph B, means the total incremental costs to the institution that are directly attributable to the addition of a new health service.
4. **APPROPRIATELY CAPITALIZED EXPENDITURES** means those expenditures that would be capitalized if the project were implemented.
5. **BED CAPACITY** means the licensed capacity of a health care facility.
6. **BED COMPLEMENT** means the total number of beds that are normally available for inpatient use. These are beds that are set up and staffed irrespective of any basic standards regarding the number of beds, but excludes beds in corridors and in other nonadaptable areas, labor, holding, emergency, anesthesia and recovery rooms.
7. **CAPITAL EXPENDITURE** means an expenditure, including a force account expenditure or predevelopment activities, that under generally accepted accounting principles is not properly chargeable as an expense of operation and maintenance and, for the purposes of this chapter, includes capitalized interest on borrowed funds and the fair market value of any property or equipment that is acquired under lease or comparable arrangement or by donation. 22 M.R.S.A. Sec. 328 (3). "Capital expenditure" includes but is not limited to organizational costs associated with a project such as legal fees related to the capital expenditure and regulatory approvals and costs associated with education, training, etc.
8. **CAPITAL INVESTMENT FUND (CIF)** means the limit on resource expenditures that may be made as part of any hospital or non-hospital project, which is established on an annual basis.
9. **COMMENCED/COMMENCEMENT.** A project shall be considered to have "commenced" when:
 - A. for the purpose or leasing of equipment, buildings, existing health care facilities, or land; the sale or lease has been consummated and the buyer or lessor is in possession and the property is being used for the purpose described in the application for which the Certificate of Need was issued,

- B. for the new construction of a health care facility, part thereof, or associated structure; all predevelopment activity necessary to meet the remaining elements of this provision has been completed, the site has been cleared, the foundation has been fully laid and at least 50% of the approved capital expenditure has been obligated, except for projects with approved capital expenditures in excess of \$10 million where at least 50% of the portion of the total capital expenditure which was originally forecast to be completed during the 12 months following the issuance of the Certificate of Need, or any extension thereto, must be obligated,
 - C. for predevelopment activities, all such activities to be completed are fully obligated and such obligation requires that they be completed within the following six months,
 - D. for modification of a health care facility not adequately covered by the above-listed requirements; all predevelopment activity necessary to meet the remaining elements of this provision has been completed and at least 50% of the approved capital expenditure has been obligated,
 - E. for new health services; the service is fully operational,
 - F. for termination of a health service; the service has been terminated and all approved capital expenditures have been obligated,
 - G. for changes in bed complement; the change has been completed.
 - H. for all projects, when the Department or the holder is defending litigation relative to the issuance of a Certificate of Need, provided that the litigation is not initiated by the holder and the holder is making a good faith effort to meet the timetable for making the service or equipment available or for completing the project specified in the approved application.
- 10. CONSTRUCTION when used in connection with "health care facility" or "major medical equipment" means the establishment, erection, building, purchase or other acquisition of a health care facility. 22 M.R.S.A. Sec. 328 (4).
 - 11. COST when used in conjunction with the review threshold for "major medical equipment," shall include capital expenditures.
 - 12. DEPARTMENT means the Department of Health and Human Services.
 - 13. DEVELOPMENT when used in connection with "health service," means the undertaking of those activities that on their completion will result in the offering of a new health service to the public. 22 M.R.S.A. Sec. 328 (5).
 - 14. EXPENDITURE MINIMUM FOR ANNUAL OPERATING COSTS means, for services commenced after October 1, 1998, \$400,000 for the 3rd fiscal year, including a partial first year. 22 M.R.S.A. Sec. 328 (6).
 - 15. EXTROADINARY PROJECT means a project subject to review under the Maine Certificate of Need Act with approved third year capital and operating costs in excess of \$2,000,000.

16. **GENERALLY ACCEPTED ACCOUNTING PRINCIPLES** means accounting principles approved by the American Institute of Certified Public Accountants or a successor organization. 22 M.R.S.A. Sec. 328 (7).
17. **HEALTH CARE FACILITY** means a hospital, psychiatric hospital, nursing facility, kidney disease treatment center including a free-standing hemodialysis facility, rehabilitation facility, ambulatory surgical facility, independent radiological service center, independent cardiac catheterization center or cancer treatment center. "Health care facility" does not include the office of a private health care practitioner, as defined in Title 24, section 2502, subsection 1-A, whether in individual or group practice. In an ambulatory surgical facility that functions also as the office of a health care practitioner, the following portions of the ambulatory surgical facility are considered to be a health care facility:
 - A. Operating rooms;
 - B. Recovery rooms;
 - C. Waiting areas for ambulatory surgical facility patients; and
 - D. Any other space used primarily to support the activities of the ambulatory surgical facility. 22 M.R.S.A. Sec. 328 (8).
18. **HEALTH MAINTENANCE ORGANIZATION** means public or private organization that:
 - A. Provides or otherwise makes available to enrolled participants health care services, including at least the following basic health services: Usual physician services, hospitalization, laboratory, x-ray, emergency and preventive health services and out-of-area coverage;
 - B. Is compensated, except for copayments, for the provision of the basic health services to enrolled participants on a predetermined periodic rate basis; and
 - C. Provides physicians' services primarily through physicians who are either employees or partners of the organization or through arrangements with individual physicians or one or more groups of physicians. 22 M.R.S.A. Sec. 328 (9) (A)-(C).
19. **HEALTH NEED** means a situation or a condition of a person, expressed in health outcome measures such as mortality, morbidity or disability, that is considered undesirable and is likely to exist in the future. 22 M.R.S.A. Sec. 328 (10).
20. **HEALTH PLANNING** means data assembly and analysis, goal determination and the formulation of action recommendations regarding health services. 22 M.R.S.A. Sec. 328 (11).
21. **HEALTH SERVICES** means clinically related services that are diagnostic, treatment, rehabilitative services or nursing services provided by a nursing facility, and includes alcohol abuse, drug abuse and mental health services. 22 M.R.S.A. Sec. 328 (12).

22. HEALTH STATUS means patient or population measures, or both, of good and poor health practices, rates of death and disease, both chronic and infectious, and the prevalence of symptoms or conditions, or both, of illness and wellness. 22 M.R.S.A. Sec. 328 (13).
23. HOSPITAL means an institution that primarily provides to inpatients, by or under the supervision of physicians, diagnostic services and therapeutic services for medical diagnosis, treatment and care of injured, disabled or sick persons or rehabilitation services for the rehabilitation of injured, disabled or sick persons. This term also includes psychiatric and tuberculosis hospitals. 22 M.R.S.A. Sec. 328 (14).
24. HOSPITAL PROJECT means a project that is being proposed by or on behalf of a hospital, as defined at 22 MRSA section 328(14), and that relates to facilities, services or equipment, that is subject to review and approval under the Maine Certificate of Need Act and rules.
25. HOSPITAL SWING BED means an acute care bed licensed by the Bureau of Medical Services, Division of Licensing and Certification, for use also as a nursing care bed. Swing beds may be established only in rural hospitals with fewer than 100 licensed acute care beds. 22 M.R.S.A. Sec. 328 (15).
26. LARGE PROJECT means a hospital or non-hospital project with third year operating costs greater than or equal to \$500,000.
27. MAJOR MEDICAL EQUIPMENT means a single unit of medical equipment or a single system of components with related functions used to provide medical and other health services that costs \$1,200,000 or more. "Major medical equipment" does not include medical equipment acquired by or on behalf of a clinical laboratory to provide clinical laboratory services if the clinical laboratory is independent of a physician's office and a hospital and has been determined to meet the requirements of the United States Social Security Act, Title XVIII, Section 1861(s), paragraphs 10 and 11. In determining whether medical equipment costs more than the threshold provided in this subsection, the cost of studies, surveys, designs, plans, working drawings, specifications, construction/renovations and other activities essential to acquiring and making the equipment functional must be included. If the equipment is acquired for less than fair market value, the term "cost" includes the fair market value. Beginning September 30, 2004 and annually thereafter, the threshold amount for review must be updated by the Commissioner to reflect the change in the Consumer Price Index, medical index. 22 M.R.S.A. Sec. 328 (16).
28. MODIFICATION means the alteration, improvement, expansion, extension, renovation or replacement of a health care facility or health maintenance organization or portions thereof, including the initial equipment and the replacement of equipment or existing buildings. 22 M.R.S.A. Sec. 328 (17).
29. NEW HEALTH SERVICE means:
 - A. The obligation of any capital expenditures by or on behalf of a health care facility of \$110,000 or more that is associated with the addition of a health service that was not offered on a regular basis by or on behalf of the healthcare facility within the 12-month period prior to the time the services would be offered.

The addition of a health service that is to be offered by or on behalf of a healthcare facility that was not offered on a regular basis by or on behalf of a healthcare facility within the 12-month period prior to the time the services would be offered and that, for the 3rd fiscal year of operation, including a partial first year following addition of that service, is projected to entail incremental annual operating costs directly attributable to the addition of that health service of at least \$400,000; or

- B. The addition in the private office of a health care practitioner, as defined in Title 24, section 2502, subsection 1-A, of new technology that costs \$1,200,000 or more. The Department shall consult with the Maine Quality Forum Advisory Council established pursuant to Title 24-A, section 6952, prior to determining whether a project qualifies as a new technology in the office of a private practitioner. Beginning September 30, 2004, and annually thereafter, the threshold amount for review must be updated by the Commissioner to reflect the change in the Consumer Price Index medical index. With regard to the private office of a health care practitioner, "new health service" does not include the location of a new practitioner in a geographic area.

"New health service" does not include a health care facility that extends a current service within the defined primary service area of the health care facility by purchasing within a 12-month time period new equipment costing in the aggregate less than the threshold provided in section 328, subsection 16.22 M.R.S.A. Sec. 328 (17-A).

- 30. NON-HOSPITAL PROJECT means a project that is being proposed by or on behalf of a health care facility as defined in 22 MRSA section 328(8), other than a hospital, that is subject to review and approval under the Maine Certificate of Need Act and rules.
- 31. NURSING FACILITY means any facility defined under section 1812-A. 22 M.R.S.A. Sec. 328 (18).
- 32. OBLIGATION for a capital expenditure is considered to be incurred by or on behalf of a health care facility:
 - A. When a contract, enforceable under the law of the State, is entered into by or on behalf of the health care facility for the construction, acquisition, lease or financing of a capital asset;
 - B. When the governing board of the health care facility takes formal action to commit its own funds for a construction project undertaken by the health care facility as its own contractor; or
 - C. In the case of donated property, on the date on which the gift is completed under applicable law of the State. 22 M.R.S.A. Sec. 328 (19) (A)-(C).
- 33. OFFER when used in connection with "health services," means that the health care facility or health maintenance organization holds itself out as capable of providing or having the means to provide a health service. 22 M.R.S.A. Sec. 328 (20).
- 34. OPERATING COSTS means the total non-capital incremental costs attributable to a project approved in accordance with the Maine Certificate of Need Act and rules.

35. PERSON means an individual; trust or estate; partnership; corporation, including associations, joint stock companies and insurance companies; the State or a political subdivision or instrumentality of the State, including a municipal corporation of the State; or any other legal entity recognized by State law. 22 M.R.S.A. Sec. 328 (21).
36. PERSON DIRECTLY AFFECTED BY A REVIEW includes:
- A. The applicant;
 - B. A group of ten (10) persons residing or located within the health service area served or to be served by the applicant;
 - C. A health care facility, a health maintenance organization or a health care practitioner that demonstrates that it provides similar services or, by timely filing a Letter of Intent with the Department for inclusion in the record, has indicated an intention to provide similar services in the future to patients residing in the health service area and whose services would be directly and substantially affected by the application under review;
 - D. A 3rd-party payor, including, without limitation, a health maintenance organization, who pays health care facilities for services in the health service area in which the project is proposed to be located and whose payments would be directly and substantially affected by approval or disapproval of the application under review; and
 - E. A person who demonstrates a direct and substantial effect upon that person's health care as a result of approval or disapproval of an application under review. 22 M.R.S.A. Sec. 328 (22)(A)-(E)
 - F. The Department will provide identified Persons Directly Affected by a Review with copies of final Department analyses and assessments during the review cycle, including copies of final assessments performed by the Bureau of Health and Bureau of Insurance.
37. PREDEVELOPMENT ACTIVITY means any appropriately capitalized expenditure by or on behalf of a health care facility made in preparation for the offering or development of a new health service for which a Certificate of Need would be required and arrangements or commitments made for financing the offering or development of the new health service and includes site acquisitions, surveys, studies, expenditures for architectural designs, plans, working drawings and specifications. 22 M.R.S.A. Sec. 328 (23).
38. PROJECT means any acquisition, capital expenditure, new health service, or change in a health service, predevelopment activity or other activity that requires a Certificate of Need under section 329. 22 M.R.S.A. Sec. 328 (24).
39. REGULAR BASIS when used in conjunction with the definition of a new health service, means offered on a routine basis in such a manner as to reasonably accommodate the diagnostic, treatment or rehabilitation needs of patients on a least a weekly basis and provided on at least 50% of the normal business days during which the service is offered within the 12-month period prior to the time the service is intended to be offered.

40. REHABILITATION FACILITY means an inpatient facility that is operated for the primary purpose of assisting in the rehabilitation of disabled persons through an integrated program of medical and other services that are provided under competent professional supervision. 22 M.R.S.A Sec. 328 (25).
41. REPLACEMENT EQUIPMENT means a piece of capital equipment that replaces another piece of capital equipment that performs essentially the same functions as the replaced equipment. 22 M.R.S.A. Sec. 328 (26). The equipment being replaced must be removed and/or discontinued from use and must not be used by the applicant or a related entity to provide medical or other health services.
42. SIGNIFICANT CHANGE IN FINANCING when used in relation to activities requiring subsequent review and approval, includes changes in the principal amount, interest rate and term of debt financing, the nature of the pay-back provisions on debt-financing (such as level-debt schedule or level-principal schedule), the amount and nature of equity contributions, the annual amount and duration of depreciation expense charges.
43. SMALL PROJECT means a hospital or non-hospital project with third year operating costs less than \$500,000.
44. STATE HEALTH PLAN means the plan developed and issued by the Governor pursuant 2 M.R.S.A. c. 5, section 101.

CHAPTER 4: THE SCOPE OF CERTIFICATE OF NEED - COVERED ACTIVITIES

Advisory Note: The Certificate of Need Unit must be contacted and supplied the information set forth in Chapter 6 on any activity regarding a non-nursing facility that may appear to require a Certificate of Need, may result in increased charges or cost to third party payors or when the estimated cost of the activity is within 5% of the applicable review threshold amount.

1. Certificate of Need Required.

- A. A person may not enter into any commitment for financing a project that requires a Certificate of Need or incur an expenditure for the project without having sought and received a Certificate of Need, except that this prohibition does not apply to obligations for financing conditioned upon the receipt of a Certificate of Need or to obligations for predevelopment activities. 22 M.R.S.A. Sec. 329.
- B. A Certificate of Need from the Department is required for:
 - (1) Transfer of ownership; acquisition by lease, donation, transfer; acquisition of control. Any transfer of ownership or acquisition under lease or comparable arrangement or through donation or any acquisition of control of a health care facility under lease, management agreement or comparable arrangement or through donation that would have required review if the transfer or acquisition had been by purchase, except in emergencies when that acquisition of control is at the direction of the Department (22 M.R.S.A. Sec. 329 (1));
 - (2) Acquisitions of major medical equipment. The use of major medical equipment on a temporary basis in the case of a natural disaster, major accident or equipment failure and the use of replacement equipment does not require a Certificate of Need. Beginning September 30, 2004 and annually thereafter, the threshold amount for review must be updated by the Commissioner to reflect the change in the Consumer Price Index medical index (22 M.R.S.A. Sec. 329 (2));
 - (3) Capital expenditures. Except as provided in subsection 6, the obligation by or on behalf of a health care facility of any capital expenditure of \$2,400,000 or more. Capital expenditures in the case of a natural disaster, major accident or equipment failure for replacement equipment or for parking lots and garages, information and communication systems and physician office space do not require a Certificate of Need; however, the capital cost of these items must be included in the total capital expenditure for a project that otherwise requires a Certificate of Need. Beginning September 30, 2004 and annually thereafter, the threshold amount for review must be updated by the Commissioner to reflect the change in the Consumer Price Index medical index (22 M.R.S.A. Sec. 329 (3));
 - (4) New health service. The offering or development of any new health service (22 M.R.S.A. Sec. 329 (4));

- (5) Changes in bed complement. An increase in the existing licensed bed complement or an increase in the licensed bed category of a health care facility, other than a nursing facility, of greater than 10% (22 M.R.S.A. Sec. 329 (5));
- (6) Nursing facilities. The obligation by a nursing facility, when related to nursing services provided by the nursing facility, of any capital expenditures of \$510,000 or more. A Certificate of Need is not required for a nursing facility to convert beds used for the provision of nursing services to beds to be used for the provision of residential care services. If such a conversion occurs, public funds are not obligated for payment of services provided in the converted beds (22 M.R.S.A. Sec. 329 (6));
- (7) Other circumstances. The following circumstances:
 - A. Any proposed use of major medical equipment to serve inpatients of a hospital, if the equipment is not located in a health care facility and was acquired without a Certificate of Need, except acquisitions exempt from review under subsection 2 or 3; or
 - B. If a person adds a health service not subject to review under subsection 4, paragraph A and not subject to review under subsection 4, paragraph B at the time it was established and not reviewed and approved prior to establishment at the request of the applicant, and its actual 3rd fiscal year operating cost exceeds the expenditure minimum for annual operating costs in the 3rd fiscal year of operation following addition of these services (22 M.R.S.A. Sec. 329 (7)); and
- (8) Related Projects. Any projects that the Department determines are related projects if such projects, considered in the aggregate, would otherwise require a Certificate of Need under this section. 22 M.R.S.A. Sec 329 (8). Projects will be deemed related if the projects are (1) expected to be commenced by the same health care facility within 12 months of each other, and (2) provide associated services within outpatient or inpatient settings or financially impact like or similar cost centers.

2. Exceptions

Notwithstanding section 329, the requirements of this Act do not apply with respect to:

- A. *Healing through prayer.* A health care facility operated by a religious group relying solely on spiritual means through prayer for healing;
- B. *Activities; acquisitions.* Activities or acquisitions by or on behalf of a health maintenance organization or a health care facility controlled, directly or indirectly, by a health maintenance organization or combination of health maintenance organizations to the extent mandated by the National Health Policy, Planning and Resources Development Act of 1974, as amended, and its accompanying regulations;

- C. *Home health care services.* Home health care services offered by a home health care provider;
- D. *Hospice.* Hospice services and programs;
- E. *Assisted living.* Assisted living programs and services regulated under chapter 1665;
- F. *Existing capacity.* The use by an ambulatory surgical facility licensed on January 1, 1998 of capacity in existence on January 1, 1998; and
- G. *Critical Access hospitals.* Conversion by a critical access hospital of acute care beds to hospital swing beds. 22 M.R.S.A. Sec. 330 (1)-(7).

3. Subsequent Review following changes in project

When a Certificate of Need has been issued and changes occur as specified in this section, a subsequent review is required.

- A. *Criteria for subsequent review.* The following activities require subsequent review and approval, if the Department has previously issued a Certificate of Need and one or more of the following circumstances occur within 3 years after the approved activity is commenced:
 - (1) There is a significant change in financing;
 - (2) There is a change affecting the licensed or certified bed capacity as approved in the Certificate of Need;
 - (3) There is a change involving the addition or termination of the health services proposed to be rendered;
 - (4) There is a change in the site or the location of the proposed health care facility; or
 - (5) There is a substantial change proposed in the design of the health care facility or the type of construction. 22 M.R.S.A. Sec. 331 (1).
- B. *Procedures for subsequent review.* Any person proposing to undertake any activity requiring subsequent review and approval shall file with the Department, within 30 days of the time that person first has actual knowledge of the circumstances requiring subsequent review, a notice setting forth the following information:
 - (1) The nature of the proposed change;
 - (2) The rationale for the change including, where appropriate, an explanation of why the change was not set forth in the original application or Letter of Intent; and
 - (3) Other pertinent detail subject to the procedures and criteria set forth in section 335.

The Department shall, within 30 days of receipt of the information, advise that person in writing whether the proposed change is approved. If not approved, the application must be treated as a new application under this Act. If approved, the Department shall amend the Certificate of Need as appropriate. 22 M.R.S.A. Sec. 331 (2).

4. Subsequent review following approval

When the Commissioner approves an application unconditionally or subject to conditions pursuant to section 335, subsection 8, the Commissioner may conduct a review to ensure compliance with any terms or conditions of the approval within 3 years after the approved activity is undertaken. In this review, the Commissioner may hold a public hearing and may consider any significant changes in factors or circumstances relied upon by the Commissioner in approving the application and significant and relevant information that either is new or was withheld by the applicant at the time of the process under section 335. If, upon review, the Commissioner determines that any terms or conditions of the approval have not been met, the Commissioner may take enforcement action consistent with this Act. 22 M.R.S.A. Sec. 332.

5. Divisions Prohibited.

A health care facility or other party required to obtain a Certificate of Need may not separate portions of a single project into components, including, but not limited to, site facility and equipment, use of multiple contracts or multiple contractors to evade the cost limitations or other requirements of Section 329. 22 M.R.S.A. Sec. 345.

6. Time Spans Specified

- A. No health care facility or other party required to obtain a Certificate of Need shall split what should properly be considered a single capital expenditure into discrete components undertaken during more than one accounting period (generally one fiscal year) to evade the cost limitations of the program. In determining whether a particular project involves a capital expenditure requiring a Certificate of Need, the Department will take into consideration the aggregate cost of any future components of such project that are proposed to be undertaken during a thirty-six (36) month period beginning on the date the obligation for the first such component is incurred.
- B. In determining whether a proposal involves licensed bed capacity changes requiring a Certificate of Need, the Department will take into separate consideration increases, decreases, redistribution and relocations occurring over two-year periods subsequent to the effective date of the program.

CHAPTER 5: IMPLICATIONS OF NONCOMPLIANCE

1. Withholding of License.

A new health care facility, as defined in section 328, is eligible to obtain a license under the applicable State law if the facility has not obtained a Certificate of Need as required by this chapter. The license of any facility does not extend to include and may not otherwise be deemed to allow the delivery of any services, the use of any equipment that has been acquired, the use of any portion of a facility or any other change for which a Certificate of Need as required by this chapter has not been obtained. Any unauthorized delivery of services, use of equipment or a portion of a facility or other change is in violation of the respective chapter under which the facility is licensed. 22 M.R.S.A. Sec. 347.

2. Withholding of Funds.

- A. No health care facility or other provider may be eligible to apply for or receive any reimbursement, payment or other financial assistance from any State agency or other 3rd-party payor, either directly or indirectly, for any capital expenditure or operating costs attributable to any project for which a Certificate of Need as required by this chapter has not been obtained. For the purposes of this section, the Department shall determine the eligibility of a facility to receive reimbursement for all projects subject to the provisions of this chapter. 22 M.R.S.A. Sec. 348.
- B. Facilities and persons subject to the provisions of this Act shall only be eligible to receive State funds for periods commencing after the Department's decision. Consequently, failure to give timely notice of intent to initiate a project subject to review in accordance with the provisions of the Act shall result in the denial of State reimbursement, payment or financial assistance for all costs related to the project for the period of time preceding the Department's decision, even if the Department ultimately decides to issue a Certificate of Need for the project.

The amount of reimbursement or payment to be denied by State agencies for failure of a provider to give timely notice will be as follows:

- (1) For projects that do not involve a capital expenditure, all operating costs related to the project for the period of time preceding the Department's decision to grant a Certificate of Need, or
- (2) For projects that involve capital expenditure, all operating costs related to the project for the period of time preceding the Department's decision to grant a Certificate of Need, and the proportion of total capital costs (including depreciation, amortization, interest and return on owner's equity) related to the project, as represented by a fraction, the numerator of which is the amount of the total capital expenditure obligated prior to the Department's decision to grant a Certificate of Need, and the denominator of which is the total capital expenditure related to the project for all accounting periods before and after the Department's decision.

3. Injunction.

The Attorney General, upon the request of the Department, shall seek to enjoin any project for which a Certificate of Need as required by this Act has not been obtained and shall take any other action as may be appropriate to enforce this chapter. 22 M.R.S.A. Sec. 349.

4. Penalty.

Whoever violates any provision of this chapter or any rate, rule or regulation pursuant to this chapter is subject to a civil penalty payable to the State of not more than \$5,000 to be recovered in a civil action. The Department may hold these funds in a special revenue account that may be used only to support Certificate of Need reviews, such as for hiring expert analysts on a short-term consulting basis. 22 M.R.S.A. Sec. 350.

CHAPTER 6: APPLICATION PROCESS FOR A CERTIFICATE OF NEED

1. Letter of Intent.

- A. Prior to filing an application for a Certificate of Need, an applicant shall file a Letter of Intent with the Department no less than 90 days prior to the anticipated review cycle. If an anticipated review cycle begins less than 90 days after the effective date of this Manual, an applicant shall file a Letter of Intent no less than 10 days prior to the beginning of the anticipated review cycle. In the case of a Letter of Intent requesting to be considered as a competing project and containing a description noting the proposal is the same or similar project to an existing Letter of Intent or application on file, the Letter of Intent shall be filed no more than 10 days after the filing of the existing Letter of Intent or application on file.

All Letters of Intent submitted will be summarized on a monthly activity reports prepared by the Department and made available to the public, including a timely posting on the Bureau of Elder and Adult Services website. The Letter of Intent forms the basis for determining the applicability of this chapter to the proposed expenditure or action. A Letter of Intent is deemed withdrawn one year after receipt by the Department, unless sooner superseded by an application, except that the applicant is not precluded from resubmitting the same Letter of Intent. 22 M.R.S.A. Sec. 337 (1). The hand-signed Letter of Intent should be mailed or delivered to the Department of Health and Human Services at the address given on Page 2.

- B. The content of the Letter of Intent must include the following:

- (1) A request for a ruling from the Department regarding the applicability of Certificate of Need Program to the proposal;
- (2) A brief description, including location, of the proposed project. To the extent practicable, the project should be described in terms that permit comparison to the scope of coverage described in Chapter 4 of this manual;
- (3) An estimate of any capital expenditure and third year operating costs of the proposed project, and anticipated utilization; and
- (4) The anticipated date of submission of an application, if one is required.

2. Application filed.

Paragraphs (1) to (3) apply in the given order to the application process for Certificate of Need.

- (1) After receiving the Letter of Intent, the Department shall issue a letter or checklist, or both, to an applicant that stipulates and clarifies what will be required in the application and specifies the applicable review cycle for the application.
- (2) Within 30 days of filing the Letter of Intent, the applicant shall meet with the Department staff in order to assist the Department in understanding

the application and to receive technical assistance concerning the nature, extent and format of the documentary evidence, statistical data and financial data required for the Department to evaluate the proposal. The Department may not accept an application for review until the applicant has satisfied this technical assistance requirement.

- (3) After receiving notice from the Department that a Certificate of Need is required for a proposed expenditure or action, if the applicant wishes to proceed with the project, the applicant must file an application for the Certificate of Need. 22 M.R.S.A. Sec 337 (2). The application should be filed and certified complete 10 days prior to the beginning of the applicable review cycle.
- (4) Non-Applicability Determinations. A determination by the Department that a Certificate of Need is not needed for a proposed capital expenditure or action permits a health care facility, health maintenance organization or person to proceed with the proposed project without risk of having applicable sanctions or other penalties imposed, provided, however, that subsequent receipt by the Department of information which indicates that a non-applicability determination was based on partial or inaccurate disclosure of relevant facts shall be cause, when applicable, for rescinding such determination and making an applicability determination. Any person who receives a non-applicability determination is required to submit the actual capital expenditure and third year operating costs to the Department as soon as they are determined in order for the Department to monitor compliance with this section.

3. Application content.

An application for a Certificate of Need must describe with specificity how the proposed project meets each of the conditions for granting a Certificate of Need required by this Act. A statement or statements that the project will meet the conditions without supporting facts backed by relevant documentation and analysis constitute sufficient cause to deny the application. An application subject to full review must contain, if available and relevant to the particular service or technology, information on health status, public health need for the service or technology, quality assurance processes and prevention programs. 22 M.R.S.A. Sec 337 (3).

4. Application complete.

An application is certified as complete when the applicant delivers to the Department a certification in writing that states that the application should be considered complete by the Department and the applicant has scheduled a public informational meeting. Subsequent to the applicant's certification under this subsection, the applicant may submit information that is responsive to any concern, issue, question or allegation of facts contrary to those in the application made by the Department or any other person. 22 M.R.S.A. Sec 337 (4).

5. Revision of an Application.

- A. Any applicant may submit a revision to an application at any time prior to the date on which the Department staff submits its final analysis to the Commissioner; provided, however, that the Department may declare the revised application a new application to be processed in accordance with the provisions of Sec. 337 of the Act. This will result in the new application being placed in a new review cycle. No new Letter of Intent will be required.
- B. As soon as practicable after receiving a revision to an application, the Department staff shall provide an analysis of the revised application and the record to the applicant, the Commissioner and any persons who request the analysis. Notice of the availability of the analysis shall be provided as set forth in Sec. 339 (3) of the Act. Written comments may be provided until the record is closed pursuant to Sec. 335 (6) of the Act. Rights to a public hearing shall be provided as set forth in Sec. 339 (2) of the Act.

6. Public notice; public informational meeting.

Within 5 business days of the filing of a certificate by an applicant that a complete Certificate of Need application is on file with the Department, the Department will give public notice that the application has been filed and that a public informational meeting has been scheduled regarding the application must be given by publication in a newspaper of general circulation in Kennebec County and in a newspaper published within the service area in which the proposed expenditure will occur. The notice must also be provided to all persons who have requested notification by means of asking that their names be placed on a mailing list maintained by the Department for this purpose. This notice must include:

- A. A brief description of the proposed expenditure or other action;
- B. A description of the review process and schedule;
- C. A statement that any person may examine the application, submit comments in writing to the Department regarding the application, and examine the entire record assembled by the Department at any time from the date of publication of the notice until the application process is closed for comment; and
- D. The time and location of the public informational meeting and a statement that any person may appear at the meeting to question the applicant regarding the project or the Department regarding the conditions that the applicant must satisfy in order to receive a Certificate of Need for the project.
- E. The Department shall make an electronic or stenographic record of the public informational meeting. 22 M.R.S.A. Sec 337 (5).

7. Voluntary withdrawal of application.

During the review period, prior to the date that Department staff submits a final report to the Commissioner, an applicant may withdraw an application without prejudice by filing written notice of the withdrawal with the Department. A withdrawn application may be

resubmitted and will be processed as an entirely new application. 22 M.R.S.A. Sec 337 (6).

8. Filing Fee.

The Department shall adopt rules setting minimum and maximum filing fees under this chapter. A nonrefundable filing fee must be paid at the time an application is filed with the Department. If the approved capital expenditure or operating cost upon which the fees were based is higher than the initially proposed capital expenditure, then the filing fee must be recalculated and the difference in fees, if any, must be paid before the Certificate of Need may be issued. 22 M.R.S.A. Sec. 337 (7).

- A. Fees shall be computed at \$1,000 per \$1,000,000, or part thereof, of the proposed capital expenditure.
- B. The minimum fee to be paid per application shall be \$5,000.
- C. The maximum fee per application will not exceed \$250,000.
- D. The maximum fee to be paid will be determined by the initial fee and any recalculation in response to changes in capital expenditures.

9. Suspension of Review.

Any applicant may request and be granted a suspension of the review process prior to the date on which the Department staff submits its final analysis to the Commissioner. Such requests for suspensions of the review process shall be for specific periods of no less than 60 days and shall total no greater than twelve months. Failure to reactivate within this time period will result in automatic withdrawal.

10. Reapplication.

A period of three years from the date of the Department's decision to deny a Certificate of Need must lapse before an applicant denied a Certificate of Need for a proposed expenditure or action can reapply for a Certificate of Need covering the same or significantly similar proposal, except whenever the Department determines that:

- A. There has been a substantial change in existing or proposed facilities or services of the type proposed in the area served or proposed to be served by the applicant;
- B. There has been a substantial change in the need for health facilities or services of the type proposed in the area served or proposed to be served by the applicant; or
- C. The project was denied solely on the basis of exceeding the amount remaining in the Capital Investment Fund in a particular year or review cycle.

11. Maintenance of a Mailing List of Persons who have Requested Notification of the Beginning of a Review.

- A. The notice shall be provided to all persons who have requested notification by means of asking that their names be placed on a mailing list maintained by the Department for this purpose.

- B. Persons wishing to receive notification by mail of the beginning of a review must so notify the Department in writing at the address given on Page 2. Such notice must clearly state the following information:
- (1) name of person (may be a corporation) to be notified,
 - (2) business title, if any,
 - (3) business name or affiliation,
 - (4) street address or postal box number,
 - (5) city, state and zip code,
 - (6) electronic mail address
- C. The Department is only obligated to provide notification of the beginning of a review for the type of project for which notification is requested.

CHAPTER 7: REVIEW PROCESS

1. Type Of Review/Notification Of Applicant.

- A. Upon certification that an application is complete and upon grouping the application with other pending applications in a review cycle, the Department shall so notify the applicant in writing.
- B. Such notice shall state the effective date of the beginning of the review, which date shall coincide with the beginning of a review cycle, and the expected date of the Department's decision, which, to the extent practicable, shall be no more than ninety (90) calendar days after the date of the beginning of the review.
- C. The review process consists of an evaluation of the project application(s) for a Certificate of Need by the Department in light of:
 - A. The application itself;
 - B. Material collected or developed by or for the Department staff to test the assertions in the application;
 - C. All comments received by any person regarding the project; and
 - D. Any other material made part of the record. 22 M.R.S.A Sec. 339 (1).

2. Review Cycles.

Hospital and non-hospital projects may be grouped for review at least once each fiscal year. The Department establishes the following review cycles for both hospital and non-hospital projects:

LOI due on or before	Review Begins	Project Type(s)
10/01	January	Large
1/01	April	Small

3. Capital Investment Fund Review Procedures

- A. The Department may not issue a Certificate of Need for a hospital or non-hospital project either large or small that is subject to the Sec. 335 of the Certificate of Need Act if the total annual third year capital and operating costs associated with the project exceed the amount credited to the Capital Investment Fund for that annual effective period, after accounting for previously approved projects. In the case of an extraordinary project, the total cost of the project shall be allocated in equal amounts over multiple years, with no one allocation exceeding \$2,000,000.

- B. The Capital Investment Fund for each annual effective period shall be that limit on resource expenditures determined by the Governor's Office of Health Policy and Finance on an annual basis. The Capital Investment Fund shall be allocated between hospital and non-hospital components, with 12.5% of the total Capital Investment Fund allocated to the non-hospital component for the first three years of operation. Within the hospital and non-hospital components of the Capital Investment Fund ten (10%) of the allocated amount shall be set aside for small projects. The Department shall allocate the Capital Investment Fund for the annual effective period among the review cycles set forth above as follows:

LOI due on or before	Review Begins	Project Type(s)	CIF Amount Allocated
10/01	January	Large	90%
1/01	April	Small	10%

- C. For the purposes of determining whether a project is classified as a hospital/non-hospital or large/small project, the Department shall estimate, using the information contained in the Letters of Intent, the total 3rd year capital and operating costs associated with each project, whether the project is proposed by or on behalf of a hospital that is subject to review under 22 M.R.S.A. Chapter 103-A or whether the project proposed is on or on behalf of a health care practitioner as defined in 24 M.R.S.A. section 2502, subsection 1-A that is subject to review under 22 M.R.S.A. chapter 103-A.
- D. Capital Investment Fund credits remaining after a small project review cycle shall be allocated to the next review cycle in which small projects are placed. Capital Investment Fund credits remaining at the end of a large project review cycle shall be allocated to the next review cycle in which large projects are placed. Capital Investment Fund allowances remaining at the end of an annual effective period shall lapse and shall not carry forward into the following annual effective period.

4. Public hearing.

The following provisions apply to a public hearing:

- A. The Commissioner or the Commissioner's designee may hold a public hearing regarding the application.
- B. The Commissioner, or the Commissioner's designee, shall hold a public hearing if 5 persons residing or located within the health service area to be served by the applicant request, in writing, that such a public hearing be held and the request is received by the Commissioner no later than 30 days following the informational meeting on the application conducted pursuant to section 337, subsection 5.
- C. An electronic or stenographic record of the public hearing must be part of the record. 22 M.R.S.A Sec. 339 (2).

- D. Public hearings will encompass all applications within the applicable review cycle.

5. Preliminary staff analyses.

As soon as practicable, the Department staff shall provide the preliminary analyses of the application and the record to the applicant, the Commissioner and any person who requests the analyses and record. Notice of the availability of the analyses must be published in a newspaper in general circulation in Kennebec County and a newspaper of general circulation serving the area in which the project is to be located and on the Department's publicly accessible site on the Internet. 22 M.R.S.A Sec. 339 (3).

A reasonable cost will be charged to any person requesting the analyses and record to cover copying and postage charges.

Written comments may be received within the Department no later than ten (10) days following publication of the availability of the preliminary staff analyses.

6. Final Department staff analysis.

A final Department staff analysis must be submitted to the Commissioner, together with the documentary record described in section 335, subsection 2, as soon as practicable after the closing of the record. 22 M.R.S.A Sec. 339 (4).

7. Reviews.

To the extent practicable, a review must be completed and the Commissioner shall make a decision within 90 days after the application has been certified as complete by the applicant. The Department shall establish criteria for determining when it is not practicable to complete a review within 90 days. Whenever it is not practicable to complete a review within 90 days, the Department may extend the review period for up to an additional 60 days. 22 M.R.S.A Sec. 339 (5).

Criteria for determining when it is not practicable to complete a review within 90 days include but are not limited to the following:

- A. Construction projects involving capital expenditures in excess of five million dollars;
- B. Proposed new health services not previously offered or issued certificates of need in the State;
- C. Letters of Intent or applications for the same or similar projects within the same review cycle;
- D. Proposals involving the construction, addition or replacement of more than 50 hospital beds; or
- E. The revision of an application during the course of the review.

8. Public Necessity.

The Department may delay action on an otherwise complete application for up to 180 days from the time the application has been certified as complete by the applicant if the Department finds that a public necessity exists. The Department shall provide written notice of the delay to the applicant and any other person who has requested in writing information regarding the application. For purposes of this subsection, the Department shall find that a public necessity exists if:

- A. The application represents a new service or technology not previously provided within the State;
- B. The application represents a potential significant impact on health care system costs;
- C. The application represents a new service or technology for which a health care system need has not been previously established; or
- D. There are several applications for the same or similar projects before the Department. 22 M.R.S.A. Sec. 339 (6).
- E. To the extent practicable, the Department shall notify Persons Directly Affected by the Review of its decision to delay action within 30 days after the application being certified complete.
- F. Any application on which the Department decides to delay action shall be placed for review in the next appropriate review cycle.

9. Simplified review and approval process.

Notwithstanding the requirements set forth in section 335, the Department shall conduct a simplified review and approval process in accordance with this section. Projects subject to the simplified review and approval process are not subject to established review cycles and need not be funded within the Capital Investment Fund.

- A. **Maintenance projects.** The Commissioner shall issue a Certificate of Need for a project that primarily involves the maintenance of a health facility if the Commissioner determines that the project:
 - (1) Will result in no or a minimal additional expense to the public or to the health care facility's clients;
 - (2) Will be in compliance with other applicable State and local laws and regulations; and
 - (3) Will significantly improve or, in the alternative, not significantly adversely affect the health and welfare of any person currently being served by the health care facility.
- B. **Life safety codes; previous Certificates of Need.** The Commissioner shall issue a Certificate of Need for a project that is required solely to meet federal, State or local life safety codes if the project involves a health facility, major medical

equipment or a new health service that has previously received a Certificate of Need.

- C. **Acquisition of control.** The Commissioner shall issue a Certificate of Need for a project that involves the acquisition of control of a health facility when the acquisition consists of a management agreement or similar arrangement and primarily involves the day-to-day operation of the facility in its current form, if the Commissioner determines that the project meets the requirements of section 335, subsection 7, paragraph B and that the project is economically feasible in light of its impact on:

- (1) The operating budget of the facility and the applicant; and
- (2) The applicant's ability to operate the facility without increases in the facility's rates beyond those that would otherwise occur absent the acquisition. 22 M.R.S.A. Sec. 336 (1)-(3).

10. **Capital expenditures.**

The Commissioner shall issue a Certificate of Need for a proposed capital expenditure upon determining that:

- A. The capital expenditure is required to eliminate or prevent imminent safety hazards, as defined by applicable fire, building or life safety codes and regulations; to comply with State licensure standards; or to comply with accreditation or certification standards that must be met to receive reimbursement under the United States Social Security Act, Title XVIII or payments under a State plan for medical assistance approved under Title XIX of that Act;
- B. The economic feasibility of the project is demonstrated in terms of its effects on the operating budget of the applicant, including its existing rate structure;
- C. There remains a public need for the service to be provided; and
- D. The corrective action proposed by the applicant is the most cost effective alternative available under the circumstances. 22 M.R.S.A. Sec. 336 (4).

A proposed capital expenditure under this section is not subject to established review cycles and need not be funded within the Capital Investment Fund.

CHAPTER 8: APPROVAL: RECORD

This section applies to determinations by the Commissioner under this chapter.

- 1. Basis for decision.** Based solely on a review of the record maintained under subsection 6 (22 M.R.S.A. Sec. 335(6)), the Commissioner shall approve an application for a Certificate of Need if the Commissioner determines that the project:

 - A. Meets the conditions set forth in subsection 7 (22 M.R.S.A. Sec. 335(7));
 - B. Is consistent with the State Health Plan;
 - C. Ensures high-quality outcomes and does not negatively affect the quality of care delivered by existing service providers;
 - D. Does not result in inappropriate increases in service utilization, according to the principles of evidence-based medicine adopted by the Maine Quality Forum, as established in Title 24-A, section 6951; and
 - E. Can be funded within the Capital Investment Fund. 22 M.R.S.A. Sec. 335 (1).
- 1-A Review cycle.** The Commissioner shall review applications periodically on a competitive basis. 22 M.R.S.A. Sec. 335 (2).
- 2. Communications.**

Except as otherwise provided in this Act, only a person who is a full-time employee of the Department with responsibilities for the Certificate of Need program, a consultant to the project or a policy expert pursuant to section 338 may communicate with the Commissioner regarding any application for a Certificate of Need or any Letter of Intent. Nothing in this section limits the authority and obligation of the staff of the Department with responsibility for the Certificate of Need program to meet with, or otherwise communicate with, any person who is not a Department employee and who wants to provide information to be considered in connection with an application for a Certificate of Need. 22 M.R.S.A. Sec. 335 (2).
- 3. Limited communications.**

A person who is not a Department employee may not communicate with any Department staff regarding the merits of a Certificate of Need application except for the purpose of placing that person's views in the application record. All communications with Department staff responsible for the Certificate of Need program from any person, who is not a Department employee, that the Department staff reasonably believes is intended to influence the analyses relating to or the decision regarding any application for Certificate of Need must be noted by that Department staff and that notation must be made part of the application record. 22 M.R.S.A. Sec. 335 (3). For purposes of this section, Department employees with responsibilities for the Certificate of Need program include but are not limited to employees of the Certificate of Need Unit and the Bureau of Health. This section shall not prohibit communication with the Certificate of Need Unit solely for the purpose of arranging a public informational meeting or public hearing as described in Chapters 6 and 7.
- 4. Decision.**

The Commissioner's determination must be in writing and must contain appropriate references to the record. If the application is denied, the decision must specifically

address comments received and made part of the record that favor granting the application. If the application is approved, the decision must specifically address comments received and made part of the record that favor denial of the application. 22 M.R.S.A. Sec. 335 (4).

5. Record.

The record created by the Department in the course of its review of an application must contain the following:

- A. The application and all other materials submitted by the applicant for the purpose of making those documents part of the record;
- B. All information generated by or for the Department in the course of gathering material to assist the Commissioner in determining whether the conditions for granting an application for a Certificate of Need have or have not been met. This information may include, without limitation, the report of consultants, including reports by panels of experts assembled by the Department to advise it on the application, memoranda of meetings or conversations with any person interested in commenting on the application, letters, memoranda and documents from other interested agencies and offices of State Government, memoranda describing officially noticed facts and any information supplied by Maine Health Data Organization;
- C. Stenographic or electronic recordings of any public hearing held by the Commissioner or the staff of the Department at the direction of the Commissioner regarding the application;
- D. Stenographic or electronic recording of any public informational meeting held by the Department pursuant to section 337, subsection 5;
- E. Any documents submitted by any person for the purpose of making those documents part of the record regarding any application for a Certificate of Need or for the purpose of influencing the outcome of any analyses or decisions regarding an application for Certificate of Need, except documents that have been submitted anonymously. Such source-identified documents automatically become part of the record upon receipt by the Department;
- F. Preliminary and final analyses of the record prepared by the staff; and
- G. Written assessments by the Director of the Bureau of Health and the Superintendent of Insurance assessing the impact of the application on the health care system or cost of health insurance in the State. 22 M.R.S.A. Sec. 335 (5).

6. Maintenance of the record.

The record created pursuant to subsection 5 first opens on the day the Department publishes its notice that an application for a Certificate of Need has been filed. From that day, all of the record is a public record under the Maine Freedom of Access Act, and any person may examine that record and purchase copies of any or all of that record during the normal business hours of the Department.

The record is closed 10 days after a public notice of the closing of the record has been published in a newspaper of general circulation in Kennebec County, in a newspaper published within the service area of the project and on the Department's publicly accessible site on the Internet, as long as such notice is not published until after the preliminary staff analysis of the application is made part of the record. 22 M.R.S.A. Sec. 335 (6).

7. Conditional approvals.

The Commissioner may grant an application subject to conditions that relate to the criteria for approval of the application. 22 M.R.S.A. Sec. 335 (8).

8. Emergency Certificate of Need.

Upon the written or oral request of an applicant, the Department shall immediately determine whether an emergency situation exists and upon finding that an emergency situation does exist shall issue a Certificate of Need for a project necessary on account of the emergency situation. The scope of the Certificate of Need may not exceed that which is necessary to remedy or otherwise effectively address the emergency situation. The Certificate of Need may be subject to conditions consistent with the purpose of this Act that do not interfere with the applicant's ability to respond effectively to the emergency. An emergency Certificate of Need is not subject to established review cycles need not be funded within the Capital Investment Fund.

The Commissioner shall find an emergency situation exists whenever the Commissioner finds that an applicant has demonstrated:

- A. The necessity for immediate or temporary relief due to a natural disaster, a fire, an unforeseen safety consideration, a major accident, equipment failure, foreclosure, receivership or an action of the Department or other circumstances determined appropriate by the Department;
- B. The serious adverse effect of delay on the applicant and the community that would be occasioned by compliance with the regular requirements of this chapter and the rules adopted by the Department; and
- C. The lack of substantial change in the facility or services that existed before the emergency situation. 22 M.R.S.A. Sec. 335 (9).

CHAPTER 9: CONSULTATION

1. Consultation on new technologies and needs.

In connection with the development of policies and procedures to implement this Act, the Commissioner may consult with persons with relevant skills and experience regarding:

- A. New medical technologies and the impact of those technologies on the health care delivery system in the State;
- B. Unmet need for health care services in the State; and
- C. The quality of health care. 22 M.R.S.A. Sec. 338.

CHAPTER 10: PRINCIPLES GOVERNING REVIEWS

1. Determinations Required.

Except as provided in section 336, the Commissioner shall issue a Certificate of Need if the Commissioner determines and makes specific written findings regarding that determination that:

- A. That the applicant is fit, willing and able to provide the proposed services at the proper standard of care as demonstrated by, among other factors, whether the quality of any health care provided in the past by the applicant or a related party under the applicant's control meets industry standards;
- B. The economic feasibility of the proposed services is demonstrated in terms of:
 - (1) Capacity of the applicant to support the project financially over its useful life, in light of the rates the applicant expects to be able to charge for the services to be provided by the project; and
 - (2) Applicant's ability to establish and operate the project in accordance with existing and reasonably anticipated future changes in federal, State and local licensure and other applicable or potentially applicable rules;
- C. There is a public need for the proposed services as demonstrated by certain factors, including, but not limited to:
 - (1) Whether, and the extent to which, the project will substantially address specific health problems, as measured by health needs in the area to be served by the project;
 - (2) Whether the project will have a positive impact on the health status indicators of the population to be served;
 - (3) Whether the services affected by the project will be accessible to all residents of the area proposed to be served; and
 - (4) Whether the project will provide demonstrable improvements in quality and outcome measures applicable to the services proposed in the project;
- D. That the proposed services are consistent with the orderly and economic development of health facilities and health resources for the State as demonstrated by:
 - (1) The impact of the project on total health care expenditures after taking into account, to the extent practical, both costs and benefits of the project and the competing demands in the local service area and statewide for available resources for health care;
 - (2) The availability of State funds to cover any increase in State costs associated with utilization of the project's services; and

- (3) The likelihood that more effective and accessible, or less costly, alternative technologies or methods of service delivery may become available.

In making a determination under this subsection, the Commissioner shall use data available in the State health plan under section 253, data from the Maine Health Data Organization established in chapter 1683 and other information available to the Commissioner. Particular weight must be given to information that indicates that the proposed health services are innovations in high quality health care delivery, that the proposed health services are not reasonably available in the proposed area and that the facility proposing the new health services is designed to provide excellent quality health care.

- E. Is Consistent with the State Health Plan. For this determination, the Commissioner will be guided by the priority criteria set forth in the State Health Plan. Those projects meeting the greatest number of criteria in any of the relevant priority groupings will be given the highest priority and consideration for approval by the Commissioner. The criteria below are listed in rank priority order.

1. Projects that protect public health and safety-

- Projects with the primary objective of eliminating threats to patient safety.
- Projects that incorporate comprehensive disease detection, treatment and rehabilitation, that show evidence of leading to decreases in inappropriate utilization, and other evidence based strategies to reduce the impact of such chronic illness as cardiovascular disease, cancer, asthma, chronic lung disease, diabetes and mental illness, furthering the goal of moving our health care system toward the chronic care model.
- Projects that reflect a redirection of resources and focus on population-based health and prevention. Such projects will allow us to move toward our goal of shifting resources toward areas of greatest need which is for prevention and care of the chronically ill.
- Projects that demonstrate best practices in building construction, renovation and operation to minimize environmental impact both internally and externally (e.g. “green” energy).

2. Projects that contribute to lower costs of care and greater efficiencies:

- Projects that will reduce future demand for health care services
- Projects that result in reduced operating costs for existing facilities.
- Projects that physically consolidate hospitals or services that serve all or part of the same area that demonstrate an appropriate, cost effective use for the “abandoned” infrastructure, that do not result in increased costs to the health care system and that, in accordance with State policy as expressed in Maine’s Growth Management Act, do not contribute to sprawl.
- Telemedicine projects that facilitate improvements and cost-efficiencies in the quality of diagnosis and treatment in smaller, rural communities.

3. Projects that advance access to services and reflect a collaborative, evidence-based strategy for introducing new services and technologies:

- Projects that make the best use of existing capacity/infrastructure in initiatives focused on expanding access to ambulatory or primary care services.
- Projects introducing new technology or services will only be considered if evidence is provided showing detailed analysis of peer reviewed research and data supporting the technology and need and clearly detailing the impact of the project on health care spending in Maine over the short, medium and long term time horizons. Projects must be recommended by the Maine Quality Forum and documented evidence of collaboration exists to assure shared use of new resources across the State, rather than proliferation and/or duplication of new technology.

In addition, high priority will be assigned to applicants able to demonstrate the following:

- Applicants demonstrating adequate evidence of good faith efforts in meeting the voluntary price and cost targets established by the Dirigo Health Reform Act, PL 469.
- Applicants demonstrating investment in and/or use of an electronic medical records system with an HL7 interface, allowing for exchange of information. This priority assignment will be available to any applicant, regardless of the project applied for. The policy rationale underlying this priority assignment is our desire to encourage implementation of the infrastructure necessary to facilitate integrated clinical information systems. Such systems will serve to improve the quality of care and , ultimately, reduce the cost of care.

Projects that involve any of the following characteristics cannot be considered priority projects:

- Projects that duplicate existing services or facilities in a region or community that has existing capacity for such services. This limitation assists in the orderly development of the health care system and in our efforts to control costs.
- Projects that result in an increase in the number of inpatient beds in the State. Putting additional beds on-line, without a complementary reduction in beds elsewhere will infuse additional costs into the system.
- Projects that involve the construction of a new hospital (other than replacement facilities).
- Projects that involve major expansions of existing services and/or facilities.

- F. Ensures high-quality outcomes and does not negatively affect the quality of care delivered by existing service providers;
- G. Does not result in inappropriate increases in service utilization, according to the principles of evidence-based medicine adopted by the Maine Quality Forum, as established in Title 24-A, section 6951;
- H. Can be funded within the Capital Investment Fund. 22 M.R.S.A. Sec. 335 (7).

To determine whether a project can be funded within the Capital Investment Fund, the Commissioner will be guided by the priority criteria set forth above.

CHAPTER 11: SCOPE OF CERTIFICATES OF NEED ISSUED

1. **Application determinative.**

A Certificate of Need is valid only for the defined scope, premises and facility or person named in the application and is not transferable or assignable. 22 M.R.S.A. Sec. 346 (1).

2. **Maximum expenditure.**

In issuing a Certificate of Need, the Department shall specify the maximum capital expenditures that may be obligated under this certificate. The Department shall adopt rules regarding the determination of capital expenditure maximums, procedures to monitor capital expenditures obligated under certificates and procedures to review projects for which the capital expenditure maximum is exceeded or expected to be exceeded. 22 M.R.S.A. Sec. 346 (2).

The allowable maximum capital expenditure for any project involving a capital expenditure shall be the amount approved by the Department, plus 5%. The amount shall not exceed \$1,000,000 unless approved by the Department.

3. **Periodic review.**

After the issuance of a Certificate of Need, the Department shall periodically review the progress of the holder of the certificate in meeting the timetable for making the service or equipment available or for completing the project specified in the approved application. A Certificate of Need expires if the project for which the certificate has been issued is not commenced within 12 months following the issuance of the certificate. The Department may grant an extension of a certificate for an additional specified time not to exceed 12 months if good cause is shown why the project has not commenced. The Department may require evidence of the continuing feasibility and availability of financing for a project as a condition for extending the life of the certificate. In addition if on the basis of its periodic review of progress under the certificate, the Department determines that the holder of a certificate is not otherwise meeting the timetable and is not making a good faith effort to meet it, the Department may, after a hearing, withdraw the Certificate of Need. The applicant shall issue to the Department periodic reports as designated in the Certificate of Need approval notification on the impact of the service on the health status, quality of care and health outcomes of the population served. These reports may not be in less than 12-month intervals following the start of service approved in the Certificate of Need, and shall be required for a minimum of 3 years. The Department shall adopt rules for the withdrawal of Certificates of Need. 22 M.R.S.A. Sec. 346 (3).

CHAPTER 12: DEPARTMENTAL RECONSIDERATION

Any person directly affected by a review under this chapter may, for good cause shown, request in writing a hearing for the purpose of reconsideration of the decision of the Department to issue or to deny a Certificate of Need.

1. **Timing for request.**

A request for hearing for reconsideration must be received within 30 days of the Department's decision. 22 M.R.S.A. Sec. 340 (1).

2. **Petition for Reconsideration.**

A person submitting a request for a hearing for reconsideration must submit all material relevant to the determination of whether a hearing should be held, including any supporting documentation, in a single, all inclusive, petition filed within 30 days of the Department's decision. Material received after the receipt of the single petition will not be considered in determining whether to hold a hearing. If the Department determines that good cause for a hearing has been demonstrated, it shall commence its hearing within 30 days of receipt of the petition requesting a hearing

3. **Hearing.**

If the Department determines that good cause for a hearing under this section has been demonstrated, the Department shall commence a hearing within 30 days of receipt of the request. For the purposes of this section, a request for a hearing is considered to show good cause if it:

- A. Presents significant, relevant information not previously considered by the Department;
- B. Demonstrates that there have been significant changes in factors or circumstances relied upon by the Department in reaching its decision;
- C. Demonstrates that the Department has materially failed to follow its adopted procedures in reaching its decision; or
- D. Provides other bases for a hearing that the Department has determined constitute good cause. 22 M.R.S.A. Sec. 340 (2).

4. **Conduct of Hearing.**

Such hearing shall be held in accordance with Title 5, Chapter 375, Subchapter IV of the Administrative Procedure Act. The scope of the hearing shall be limited to the issue(s) that the Department determines constitute good cause for the purpose of commencing the hearing. After the close of the hearing, the hearing officer shall promptly forward the hearing record to the Commissioner for the Commissioner's consideration in rendering a decision.

5. Decision.

A decision must be rendered within 60 days of the commencement of a hearing under this section, except that the parties may agree to a longer time period. 22 M.R.S.A. Sec. 340 (3).

CHAPTER 13: JUDICIAL REVIEW

1. **Remedy.**

Any person aggrieved by a final decision of the Department made under the provisions of this Act is entitled to review in accordance with this chapter and with Title 5, chapter 375, subchapter VII.

2. **Finality.**

A decision of the Department to issue a Certificate of Need or to deny an application for a Certificate of Need is not considered final until the Department has taken final action on a request for reconsideration under section 340. A decision by the Department is not final when opportunity for reconsideration exists with respect to matters involving new information or changes in circumstances pursuant to section 340, subsection 2, paragraphs A and B. 22 M.R.S.A. Sec. 341 (1).

CHAPTER 14: IMPLEMENTATION REPORTS

The holder of a Certificate of Need shall make written reports as provided in this section and as required by rule adopted by the Department.

1. **Final plans and specifications.**

A holder of a Certificate of Need that has been issued for the construction or modification of a facility or portion of a facility shall file final plans and specifications for the project as required by the Department to determine that the plans and specifications are in compliance with the Certificate of Need and with applicable licensure, life safety code and accreditation standards.

2. **Periodic reports.**

Periodic reports must be filed at the end of each 6-month period following the issuance of a Certificate of Need under section 335, subsection 7 or section 336 regarding implementation activities, obligations incurred and expenditures made and any other matters as the Department may require.

3. **Summary reports.**

A summary report must be made when the service or services for which a Certificate of Need was issued becomes operational.

4. **Cost and utilization reports.**

For a period of one year following the implementation of the service or services for which the Certificate of Need was granted, the holder of the Certificate of Need shall file, at 6-month intervals, reports concerning the costs and utilization.

5. **Department action.**

The Department may revoke any Certificate of Need the Department has issued when the person to whom it has been issued fails to file reports or plans and specifications required by this section on a timely basis. The Department shall review services that fall below the required volume and quality standards of a Certificate of Need. 22 M.R.S.A. Sec. 350-C (1)-(5).

CHAPTER 15: OTHER PROVISIONS

1. Conflict of Interest.

In addition to the limitations of Title 5, section 18, a member or employee of the Department who has a substantial economic or fiduciary interest that would be affected by a recommendation or decision to issue or deny a Certificate of Need or who has a close relative or economic associate whose interest would be so affected is ineligible to participate in the review, recommendation or decision-making process with respect to any application for which the conflict of interest exists. 22 M.R.S.A. Sec. 344.

2. Public Information.

The Department shall prepare and publish at least annually a report on its activities conducted pursuant to this Act. The annual report must include information on all Certificates of Need granted and denied. With regard to all certificates granted on a conditional basis, the report must include a summary of information reported pursuant to section 332 and any accompanying statements by the Commissioner or Department staff submitted regarding the reports. 22 M.R.S.A. Sec. 343.

3. Cost-of-living adjustment.

Every 2 years, beginning January 1, 2005, the Department shall review the monetary figures contained in this chapter. The Department shall revise those figures to correspond to changes in the Consumer Price Index medical index by adopting rules setting the new figures. 22 M.R.S.A. Sec. 350-A.

4. Federal funding.

The Department is authorized to accept any federal funds to be used for the purposes of carrying out this chapter. 22 M.R.S.A. Sec. 350-B.

STATUTORY AUTHORITY: 22 M.R.S.A., §1, §3 and §42(1) and 312.

EFFECTIVE DATE:

September 1, 1978

AMENDED:

April 28, 1982

April 13, 1983

April 15, 1984 - Section 7.2 B, C & E

July 3, 1984 - Section 4 (1) (B)

October 8, 1984 - Chapter 2, 4, Appendix B & C

October 16, 1984 - Chapter 7 & Appendix E

June 8, 1985 - Chapter 7(2)

Chapter 4 Sec. 1B(4)(c)(iii) & Appendix B (Page 4) Repealed (Ruled invalid by Superior Court
(see memo & court ruling attached to historical copy of amendment (84-344)

April 22, 1987 - Appendix El

April 22, 1987 - Appendix En (added)

May 6, 1989 - Ch. 6 (2), 7(9C), 8(2)

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CORRECTION:

December 4, 1998 - added APA Office Notes to pages 25 and 47.

REPEALED AND REPLACED:

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